K041531

AUG - 3 2004

510(k) Summary of Safety and Effectiveness

Date Prepared:	April 30, 2004
Submitted:	Asahi Intecc Co., Ltd.
	1703 Wakita-cho, Moriyama-ku, Nagoya,
	Aichi, 463-0024, Japan
Contact Person:	Yoshi Terai
	Director of Asahi Intecc US Office
Phone Number:	Phone : (949)756-8252
Fax Number:	Fax : (949)756-8165
Device Trade Name:	Asahi Wire Asahi PTCA Guide Wire Confianza Pro
Classification Name:	Catheter Guide Wire, Class II (21 CFR 870.1330)
Predicate Device:	JoWire Neo's PTCA Guide Wire K022762
	JoWire Asahi PTCA Guide Wire K031277

Device Description:

The Asahi PTCA Guide Wire Confianza Pro is steerable guide wire with a maximum diameter of 0.014" and available in 180 cm and 300 cm length. The extension wire is connected to the end of the guide wire outside the body. The wire is constructed from a stainless steel core wire. The core wire and coil are soldered. The distal end of the guide wire has a radiopaque tip that is available straight and is made soft to easily bend with the vessel curve. The coating (hydrophilic and silicone) is applied to the distal portion of the wire guide wire. The proximal section of the guide wire is coated with PTFE.

Intended Use:

The Asahi PTCA Guide wire Confianza Pro is intended to facilitate the placement of balloon dilatation Catheter during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Asahi PTCA Guide Wires are not to be used in the cerebral blood vessel

Device Technological Characteristics and Comparison to Predicate Device:

The Asahi PTCA Guide Wire Confianza Pro is made of the same materials, available in the same diameters and lengths, have the same design and indications for use as the predicate devices and other currently marketed PTCA Guide Wires.

Performance Data:
Bench and biocompatibility testing were conducted according to the recommendations from relevant FDA guidance to demonstrate that the Asahi PTCA Guide Wire Confianza Pro met the acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing.

Conclusion:
The Asahi PTCA Guide Wire Confianza Pro is substantially equivalent to the claimed predicates devices and other currently marketed PTCA Guide Wires.

K041531

Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Asahi Intecc Co., Ltd.
c/o Mr. Yoshi Terai
Director of Asahi Intecc US Office
1703 Wakita-cho, Moriyama-ku, Nagoya
Aichi, 463-0024, Japan

Re: K041531
Trade Name: Asahi PTCA Wire Confianza Pro
Regulation Number: 21 CFR 870.1330
Regulation Name: Guide, Catheter
Regulatory Class: Class II (two)
Product Code: DQX
Dated: July 15, 2004
Received: July 22, 2004

Dear Mr. Terai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochmel

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041531

Device Name: Asahi PTCA Guide Wire Confianza Pro

Indications For Use:

To facilitate the placement of balloon dilatation catheters during perculaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Asahi PTCA Guide Wires are not to be used in the cerebral blood vessel.

The intended use and indications for use of the modified device as described in this labeling have not change. The fundamental scientific technology of the modified device has not changed.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochnel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041531